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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/736,048	12/15/2003	David E. Lowery	PHRM0002-104(6297.1.DV1)	5604
34135	7590	06/19/2007		
Pepper Hamilton LLP 500 Grant Street One Mellon Bank Center, 50th Floor Pittsburgh, PA 15219-2502			EXAMINER LI, RUIXIANG	
			ART UNIT 1646	PAPER NUMBER
			MAIL DATE 06/19/2007	DELIVERY MODE PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	Application No. 10/736,048	Applicant(s) LOWERY ET AL.	
	Examiner Ruixiang Li	Art Unit 1646	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 06 April 2007.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 63-83 is/are pending in the application.
- 4a) Of the above claim(s) 65-68 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 63, 64, 69-71 and 73-78, 80-82 is/are rejected.
- 7) ☒ Claim(s) 72, 79 and 83 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |   |   |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)  | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date <u>12/22/2006</u> . | 6) <input type="checkbox"/> Other: _____  |

## **DETAILED ACTION**

### **Status of Application, Amendments, and/or Claims**

Applicants' response filed on 04/06/2007 has been entered in full. Claims 63, 64, 69, 72, and 79 have been amended. Claim 83 has been added. Claims 63-83 are pending. Claims 63, 64, and 69-83 are under consideration.

### **Information Disclosure Statement**

The Information Disclosure Statement submitted on 12/22/2006 has been received by the Office and the listed references have been considered by the Examiner.

### **Claim Rejections under 35 USC § 112, 1<sup>st</sup> paragraph, Written Description**

(i). The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

(ii). Claims 63, 64, 69-71, 73-78, and 80-82 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors, at the time the application was filed, had possession of the claimed invention.

Applicants argue that as amended, the claims clearly require that the DmGPCR4 has a specific function and structure: it binds to allatostatin and has at least 90% homology to SEQ ID NO: 8. Applicants argue that the specification clearly demonstrates that applicants were in possession of the claimed invention at the time the application was filed. Applicants further argue that one skilled in the art would recognize that Applicants were in possession of the claimed invention at the time of filing the application.

Applicants' argument has been fully considered, but is not deemed to be persuasive because the specification merely discloses a single DmGPCR4 set forth in SEQ ID NO: 8, which is not a representative number of the DmGPCR genus encompassed in the claims. Moreover, the instant disclosure fails to provide definitive structural features of the genus of DmGPCR4 receptors. There is no description of the conserved regions that are critical to the structure and function of the genus of DmGPCR4 receptors. There is no description of the sites at which variability may be tolerated and there is no information regarding the relation of structure to function. Furthermore, the prior art does not provide compensatory structural or correlative teachings to enable one skilled in the art to identify the encompassed DmGPCR4 receptors. Accordingly, one skilled in the art would not recognize from the disclosure that the applicant was in possession of the genus of DmGPCR4 receptors and thus the claimed methods.

**Claim Rejections under 35 USC §112, 2<sup>nd</sup> paragraph**

(i). The following is a quotation of the second paragraph of 35 U.S.C. 112:

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The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

(ii). Claims 75, 76, and 82 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 75, 76, and 82 are indefinite because they recite "one or more properties of the binding modulator". It is not clear what properties of the binding modulator are referred to. Neither the specification nor the art define the term unambiguously, rendering the claims indefinite.

Referring to the specification at page 49-50, Applicants argue that the claims are clear and definite. One of skilled in the art would readily appreciate the metes and bounds of the claimed subject matter.

Applicants' argument has been fully considered, but is not deemed to be persuasive because the specification does not define "one or more properties of the binding modulator" unambiguously, the metes and bounds are not clear. Since it is not clear what properties of the binding modulator are referred to, the claims are indefinite.

### **Claim Objections**

Claims 63, 64, 70-82 are objected to because they recite non-elected subject matter (non-elected SEQ ID NO for allatostatin).

Claim 83 is objected to because it depends from objected claim 73.

Appropriate correction is required.

### **Conclusion**

No claims are allowed.

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ruixiang Li whose telephone number is (571) 272-0875. The examiner can normally be reached on Monday through Friday from 8:30 am to 5:00 pm. If attempts to reach the examiner by telephone are unsuccessful, the examiner's

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supervisor, Gary Nickol, can be reached on (571) 272-0835. The fax number for the organization where this application or proceeding is assigned is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, please contact the Electronic Business Center (EBC) at the toll-free phone number 866-217-9197.



Ruixiang Li, Ph.D.  
Primary Examiner  
June 13, 2007

RUIXIANG LI, PH.D.  
PRIMARY EXAMINER